

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 16 MAY 2006

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Applicant's or agent's file reference 40073PC/GC	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/AU2005/000063	International filing date (<i>day/month/year</i>) 21. January 2005	Priority date (<i>day/month/year</i>) 23 January 2004	
International Patent Classification (IPC) or national classification and IPC Int. Cl. A61B 5/154 (2006.01)			
Applicant MEDIGARD LIMITED et al			

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
 - a. ☒ (*sent to the applicant and to the International Bureau*) a total of 3 sheets, as follows:
 - ☒ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - b. ☐ (*sent to the International Bureau only*) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:

<input checked="" type="checkbox"/> Box No. I	Basis of the report
<input type="checkbox"/> Box No. II	Priority
<input type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/> Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/> Box No. VI	Certain documents cited
<input type="checkbox"/> Box No. VII	Certain defects in the international application
<input type="checkbox"/> Box No. VIII	Certain observations on the international application

Date of submission of the demand 15 August 2005	Date of completion of this report 28 April 2006
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer XAVIER GISZ Telephone No. (02) 6283 2064

Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

☒ The international application in the language in which it was filed

☐ A translation of the international application into _____, which is the language of a translation furnished for the purposes of:

☐ international search (under Rules 12.3(a) and 23.1 (b))

☐ publication of the international application (under Rule 12.4(a))

☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

☐ the international application as originally filed/furnished

☒ the description:

pages **1-16** as originally filed/furnished

pages* received by this Authority on _____ with the letter of

pages* received by this Authority on _____ with the letter of

☒ the claims:

pages as originally filed/furnished

pages* **17-19** as amended (together with any statement) under Article 19

pages* received by this Authority on _____ with the letter of

pages* received by this Authority on _____ with the letter of

☒ the drawings:

pages **1/8 – 8/8** as originally filed/furnished

pages* received by this Authority on _____ with the letter of

pages* received by this Authority on _____ with the letter of

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages

☐ the claims, Nos.

☐ the drawings, sheets/figs

☐ the sequence listing (*specify*):

☐ any table(s) related to the sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages

☐ the claims, Nos.

☐ the drawings, sheets/figs

☐ the sequence listing (*specify*):

☐ any table(s) related to the sequence listing (*specify*):

* If item 4 applies, some or all of those sheets may be marked "superseded."

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-9	YES
	Claims 10	NO
Inventive step (IS)	Claims 1-9	YES
	Claims 10	NO
Industrial applicability (IA)	Claims 1-10	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

The following documents identified in the International Search Report have been considered for the purposes of this report:

D2.... US 6,572,565

Novelty (N) Claim 10

Claim 10: D2 discloses a blood sampling assembly with a retractable needle. The needle holder and attached needle are held in the cylinder (10) by tabs (20). To retract the needle the health care worker inserts, and rotates the tube (62) relative to cylinder (10) and the needle holder and needle are automatically withdrawn into the tube (62) (column 8 lines 38 to 43).

Inventive Step (IS) Claim 10

Claim 10 also lacks an inventive step for the reasons given above.

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CLAIMS

1. A blood collection device comprising a housing having an open rear end adapted to accommodate an evacuated blood collecting tube, and a front end, a
5 needle holder in the front end, a needle which is attached to the needle holder and which is double ended and has a first end (outer end) that projects from the housing and a second end (inner end) that projects into the housing, the needle holder being releasably attached relative to the housing to enable the needle holder and the attached
10 needle to be retracted, and a needle retraction device, the needle retraction device able to be pushed into the housing to release the needle holder from the housing and to retract the needle holder containing the attached needle into the needle retraction device, wherein the needle holder contains at least one finger member that engages relative to the housing to retain the needle holder to the housing, the finger member being deflectable between a locking position where the finger member retains the
15 needle holder to the housing, and a release position where the needle holder can be retracted into the housing.

2. The device as claimed in claim 1, wherein the needle holder comprises an assembly of at least two parts, the first part being an inner part and containing a passageway through which a puncture needle can extend to fit the puncture needle to
20 the inner part, the second part comprising an outer nosepiece, the at least one finger member being attached relative to the nosepiece.

3. The device as claimed in claim 2, wherein the needle retraction device comprises an elongate hollow body which contains a vacuum and which has an open end, a piston which closes off the open end of the elongate hollow body and which is
25 adapted for sliding movement within the hollow body, and which is releasably attached relative to the open end.

4. The device as claimed in claim 3, wherein the piston comprises at least one finger member which releasably attaches the piston relative to the one end of the hollow body, the finger member being movable between a locking position where the
30 piston is attached to the hollow body, and a release position where the piston can be retracted into the hollow body under the influence of the vacuum.

5. The device as claimed in claim 4, wherein the at least one finger member on the piston extends forwardly from the piston, and the at least one finger

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member on the needle holder extends rearwardly such that as the needle retraction device is pushed against the rear of the needle holder, the at least one finger member on the piston releases the at least one finger member on the needle holder, and engages to the at least one finger member on the needle holder.

5 6. The device as claimed in claim 5, wherein the housing is provided with a ramp in a forward portion of the housing, the ramp contacting the at least one finger member on the piston when the needle retraction device is pushed against the rear of the needle holder, the at least one finger member riding along the ramp to release the
10 piston containing the attached needle holder to be retracted into the hollow body under the influence of vacuum.

7. The device as claimed in claim 6, wherein the piston contains a pierceable material that is pierced by the inner end of the needle when the needle retraction device is pushed against the rear of the needle holder to seal the inner end
15 of the needle.

8. The device as claimed in claim 7, wherein the piston contains a speed controller to control a speed of retraction of the piston into the hollow body, the speed controller comprising a sealing member extending from the piston and sealingly engaging with the hollow body to increase the frictional force of the piston on the
20 hollow body.

9. A blood collection device comprising a housing having an open rear end adapted to accommodate an evacuated blood collecting tube, and a front end, a needle holder in the front end, a needle which is attached to the needle holder and which is double ended and has a first end (outer end) that projects from the housing
25 and a second end (inner end) that projects into the housing, the needle holder being releasably attached relative to the housing to enable the needle holder and the attached needle to be retracted, wherein the needle holder contains at least one finger member that engages relative to the housing to retain the needle holder to the housing, the finger member being deflectable between a locking position where the finger member
30 retains the needle holder to the housing, and a release position where the needle holder can be retracted into the housing.

10. A blood collection device comprising a housing having an open rear end adapted to accommodate an evacuated blood collecting tube, and a front end, a

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5 needle holder in the front end, a needle which is attached to the needle holder and which is double ended and has a first end (outer end) that projects from the housing and a second end (inner end) that projects into the housing, the needle holder being releasably attached relative to the housing to enable the needle holder and the attached needle to be retracted, with the proviso that the needle holder is releasably attached to the housing using a positive locking action and by frictional engagement.